

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Dkt. No. 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO: All Actions Against Saint Thomas Entities	

**PLAINTIFFS’ STEERING COMMITTEE’S REPLY TO SAINT THOMAS ENTITIES’
RESPONSE IN OPPOSITION TO THE PSC’S MOTION TO QUASH SUBPOENA,
NOTICE, AND DOCUMENT REQUESTS TO DR. PHILIP J. AUSTIN, PH.D.**

The Plaintiffs’ Steering Committee (“PSC”), herby submits its Reply to Saint Thomas Entities’ (“Saint Thomas”) Response in Opposition dated July 24, 2015.¹ The PSC maintains that Saint Thomas’s subpoena and document production requests are deficient and should be quashed by the Court for the reasons set forth in its motion dated July 7, 2015.² Additionally, the case law cited by Saint Thomas does not support its position here –where the expert declaration was submitted in a set of completely different cases in which the party seeking the testimony was not a party and had no interest. Further, Saint Thomas has provided no evidence to support their contention that extraordinary circumstances exist. They provide nothing to support the contention that Dr. Austin is the only person who can testify to the condition of the cleanroom ceilings in 2012 or that the condition of the cleanroom ceilings were any different when their own experts visited the facility in 2014 (or even that the condition of the ceilings is, for any reason, different today).

¹ In accordance with MDL Order No. 11: Standing Order Governing Certain Procedural Issues [Dkt. 1524], the Saint Thomas Entities do no oppose the filing of this reply.

² Dkt. No. 2069.

A. Case law cited by Saint Thomas does not support the contention that Dr. Austin is a testifying expert in cases against Saint Thomas.

Liberty's Motion for Summary Judgment was only filed in individual Indiana cases. The Austin Declaration was filed to support the PSC's opposing positions in those Indiana cases. The Tennessee clinics were obviously not parties to those cases.³ The Austin Declaration was strictly used to support the PSC's arguments against summary judgment under Indiana substantive law of negligence in those 98 Indiana cases. This point was acknowledged by Judge Zobel's Order which stated "All the plaintiffs were injured in Indiana, and nearly all the Plaintiffs live in Indiana...Thus on the facts here, under both Massachusetts and Indiana law, Indiana substantive law applies."⁴

The Saint Thomas Entities were not named as defendants in any of those Indiana cases. Saint Thomas themselves has argued that because they were not a party to any of the Indiana cases, "Liberty's motion for summary judgment does not concern any case in which the Saint Thomas Entities are parties. Accordingly, as non-parties to those proceedings, the Saint Thomas Entities lack standing to participate in that briefing."⁵ Saint Thomas has provided no authority to support the notion that they should be allowed to obtain discovery from the PSC's consulting expert used strictly in cases where Saint Thomas had no interest in the outcome. None of the case law cited by Saint Thomas supports the contention that the declaration of a consulting expert filed in separate (now settled) cases (subject to another state's non-controlling law) against different unrelated defendants (Liberty), turns him into a testifying expert in cases against Saint Thomas.

³ Liberty's Motion for Summary Judgment stated, "There are currently 98 cases pending against Liberty in which the Plaintiffs were allegedly injected with MPA in Indiana. All but one of these matters are the subject of Liberty Industries, Inc.'s Omnibus Motion for Summary Judgment on All Cases Filed by Plaintiffs Injured in Indiana." Dkt. No. 1471 p. 1.

⁴ Dkt. No. 1613, p. 5.

⁵ Dkt. No. 1567, p. 1.

B. Saint Thomas offers no evidence that Dr. Austin's observations in 2012 create exceptional circumstances or that there is any reason to believe the cleanroom ceilings are any different today than they were in 2012.

Saint Thomas contends that Dr. Austin and his father are “the only fact witnesses who can testify about the state and condition of the NECC ceiling in 2012.” This statement is untrue. Many other people observed the NECC ceiling in 2012. Presumably, Saint Thomas has made no effort to locate them.

More important however, Saint Thomas uses quotes from PSC members seeking permission for the inspection in 2012 and from the Bankruptcy Trustee's counsel seeking to block access in 2014, to bolster its argument that somehow only testimony from Dr. Austin about his observations and opinions formed in 2012 can provide the “answers as to how and why the MPA at NECC was contaminated.”⁶ But Dr. Austin himself disavowed any ability to opine on exactly how the MPA was contaminated:

As with any biological contamination event, such as that which occurred with the contaminated vials of MPA at NECC, there are a number of possible causes. Sufficient evidence exists to conclude that the fungal contamination occurred during some aspect of the compounding process at NECC. Due to the number of possible causes for the contamination during the compounding process, it is unlikely that any definitive path of fungal contamination from an originating source to its final destination in the vials will be able to be identified. At best, only after a thorough investigation process, likely contamination paths can be identified and assigned various levels of probability.⁷

The PSC's desire to do a prompt inspection of the NECC facility has no bearing on whether the ceiling of the cleanroom is in a different condition, even today. It provides no evidence that the relevant properties of the cleanroom ceiling (its design and installation) have changed over time. There is no suggestion that the cleanrooms were altered between 2012, when

⁶ Opposition at 15.

⁷ Dkt. No. 1651-1, p. 22.

Dr. Austin visited the facility, and 2014 when Saint Thomas conducted its own inspection, or that that there has been any attempt by anyone to alter those ceilings since NECC was shuttered by state and federal officials in 2012.

The factors cited by Saint Thomas have no bearing on the physical condition of the ceilings. For instance, the fact there has been no air conditioning may be relevant if one is testing for mold or sampling air quality – which were not the subject of Dr. Austin’s report and something he is not qualified to perform – but it does not change the position of ceiling tiles or lessen or increase potential gaps between those tiles. It does not alter the fundamental design and installation of the ceiling and ceiling tile grid installed by Liberty. The fact that there has been no positive air pressure in the cleanrooms and no one working in the cleanrooms as cited by Saint Thomas actually means there has been no air flow to move or disrupt the ceiling tiles since NECC shut its operations in 2012.

Saint Thomas suggests that quotes from counsel representing the NECC estate seeking (unsuccessfully) to block inspection of the facility by Saint Thomas and other to the facility in 2014 support their contention that Dr. Austin’s observations in December 2012 are probative of conditions in the summer of 2012 when the contaminated MPA was compounded. However, in December 2012, counsel for NECC argued that there was no value in allowing Plaintiffs’ experts, such as Dr. Austin and others, access to the NECC facility because conditions in December 2012 were not indicative of conditions in the summer of 2012.⁸

Saint Thomas provides no evidence that Dr. Austin’s observations and opinions are unique or that the physical layout, design or installation of the cleanroom ceilings are affected by

⁸ Tr. of Hearing on December 10, 2012 at 30. “And so your question was whether there was going to be scientifically-valid information ascertained through this testing, and I would submit to you that there would not to be scientifically-valid information ascertained, because too much has changed.”

the passage of time such that Dr. Austin's observations and opinions, and only his observations and opinions, can provide the evidence Saint Thomas seeks.

C. The PSC has provided all documentation, including pictures and video, taken or generated as a result of the 2012 inspection.

As previously noted, the PSC has provided to Saint Thomas and all interested parties all the information, including pictures and an approximately four hour video of the NECC facility, generated during their experts' inspection. To the degree that Saint Thomas seeks to authenticate those materials, the PSC would, subject to the details of any written stipulation, agree to stipulate to the authenticity of those materials for use by Saint Thomas in lieu of a deposition of Dr. Austin, further obviating the need for his testimony.

CONCLUSION

For the reasons stated herein, PSC requests that the Court quash the subpoena, notice, and production requests of Saint Thomas, in accordance with PSC's objections.

Dated: August 4, 2015

Respectfully submitted,

/s/ Thomas M. Sobol

Thomas M. Sobol

Kristen A. Johnson

HAGENS BERMAN SOBOL SHAPIRO LLP

55 Cambridge Parkway, Suite 301

Cambridge, MA 02142

Telephone: (617) 482-3700

Facsimile: (617) 482-3003

tom@hbsslaw.com

kristenj@hbsslaw.com

Plaintiffs' Lead Counsel

Elizabeth J. Cabraser
Mark P. Chalos
Annika K. Martin
LIEFF CABRASER HEIMANN &
BERNSTEIN, LLP
150 Fourth Avenue North, Suite 1650
Nashville, TN 37219-2417
Telephone: 615.313.9000
Facsimile: 615.313.9965
ecabraser@lchb.com
mchalos@lchb.com
akmartin@lchb.com

Federal/State Liaison

Marc E. Lipton
LIPTON LAW
18930 W. 10 Mile Road
Southfield, MI 48075
Telephone: (248) 557-1688
Facsimile: (248) 557-6344
marc@liptonlawcenter.com

Kim Dougherty
JANET, JENNER & SUGGS, LLC
31 St. James Avenue, Suite 365
Boston, MA 02116
Telephone: (617) 933-1265
kdougherty@myadvocates.com

Patrick T. Fennell
CRANDALL & KATT
366 Elm Avenue, S.W.
Roanoke, VA 24016
Telephone: (540) 342-2000
pfennel@crandalllaw.com

Mark Zamora
ZAMORA FIRM
6 Concourse Way, 22nd Floor
Atlanta, GA 30328
Telephone: (404) 451-7781
Facsimile: (404) 506-9223
marc@markzamora.com

J. Gerard Stranch, IV
Benjamin A. Gastel
BRANSETTER, STRANCH & JENNINGS
PLLC
227 Second Avenue North
Nashville, TN 37201
Telephone: (615) 254-8801
Facsimile: (615) 255-5419
gerards@branstetterlaw.com
beng@branstetterlaw.com

Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, Thomas M. Sobol, hereby certify that I caused a copy of the above to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: August 4, 2015

/s/ Thomas M. Sobol

Thomas M. Sobol, BBO # 471770